UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v. Case No: 5:23-cv-576-JSM-PRL

WELLS PHARMACY NETWORK, LLC,

Defendant.

ORDER

THIS CAUSE comes before the Court upon Defendant's Motion to Dismiss (Dkt. 23), Plaintiff's Response in Opposition (Dkt. 24), and Defendant's Reply (Dkt. 28). The Court, having reviewed these filings, and being otherwise advised in the premises, concludes that Defendant's motion should be granted because Plaintiff's claim is preempted. The Court also concludes that further amendment is futile and dismisses this action with prejudice.

BACKGROUND

In its Amended Complaint,[1] Plaintiff Eli Lilly and Company seeks to enjoin Defendant Wells Pharmacy Network, LLC from selling compounded tirzepatide under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") and the Florida Drug and

[1] Plaintiff filed its initial Complaint on September 19, 2023. Defendant then filed its motion to dismiss. In response, Plaintiff filed an Amended Complaint, which is the operative pleading, and Defendant filed another motion to dismiss which is now before the Court.

Cosmetic Act ("DCA") because Wells Pharmacy's compounded products are "unapproved new drugs" that have not been formally approved by the United States Food and Drug Administration ("FDA"). Lilly alleges that Wells Pharmacy cannot avail itself of the exemption available to compounders because Wells Pharmacy does not comply with FDCA section 503A's prescription requirement.

Specifically, Lilly sells Mounjaro® and Zepbound®, the only FDA-approved drugs containing tirzepatide. Wells Pharmacy sells competing "compounded" drug products that purport to contain tirzepatide but are not FDA-approved. Florida's health and safety statute prohibits the sale of new drugs "unless an approved application has become effective under s. 505 of the [FDCA, 21 U.S.C. § 355] or unless otherwise permitted by the Secretary of the United States Department of Health & Human Services for shipment in interstate commerce." § 499.023, Fla. Stat.

FDUTPA protects the public from unfair trade practices, allowing private parties—including competitors—to sue for violations of state laws that proscribe such practices. Lilly contends that it brought this action under FDUTPA to "stop Wells from engaging in unfair trade practices by unlawfully making, selling, and distributing unapproved new drugs in Florida."

Wells Pharmacy moves to dismiss the Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

MOTION TO DISMISS STANDARD

Rule 12(b)(6) allows a complaint to be dismissed for failure to state a claim on which relief can be granted. When reviewing a motion to dismiss, courts must limit their

consideration to the well-pleaded allegations, documents central to or referred to in the complaint, and matters judicially noticed. *See La Grasta v. First Union Securities, Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (internal citations omitted); *Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005). Furthermore, they must accept all factual allegations contained in the complaint as true and view the facts in a light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 93–94 (2007).

Legal conclusions, though, "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 664 (2009). In fact, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003). To survive a motion to dismiss, a complaint must instead contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (internal quotation marks and citations omitted). This plausibility standard is met when the plaintiff pleads enough factual content to allow the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (internal citations omitted).

DISCUSSION

Wells Pharmacy's motion to dismiss asserts three reasons in favor of dismissal. First, as a threshold matter, Wells asserts that Lilly cannot demonstrate Article III standing and the requirements necessary for injunctive or declaratory relief. Second, even if Lilly could establish a concrete, real, and imminent future harm, Wells argues Lilly's claim is preempted by federal statute, the Food Drug and Cosmetic Act, 21 U.S.C.S. § 301 et seq. (the "FDCA"). Third, even assuming Lilly can overcome these initial hurdles, Wells

contends Lilly's Amended Complaint fails to plausibly allege a claim under the FDUTPA. The Court addresses these arguments in turn.

I. Standing

Article III standing requires plaintiffs to demonstrate that: (1) they suffered an "injury-in-fact;" (2) there is a causal connection between the asserted injury-in-fact and the challenged action of the defendant; and (3) "the injury will be redressed by a favorable decision." *Shotz v. Cates*, 256 F.3d 1077, 1081 (11th Cir. 2001). Injury-in-fact requires a plaintiff to show "he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016). A concrete injury is "real, and not abstract." *Id.* at 340. A particularized injury "affect[s] [a] plaintiff in a personal and individual way." *Id.* at 339. Notably, economic injury is sufficient to establish standing. *Debernardis v. IQ Formulations LLC*, 942 F.3d 1076, 1084 (11th Cir. 2019).

The Court concludes that the Amended Complaint's allegations are sufficient to establish Lilly's standing. Lilly alleged that it has lost and is losing sales because of Wells's conduct. Specifically, Lilly alleged that it "is the only supplier in the United States of FDA-approved tirzepatide drugs," and that "[s]ome sales made by [Wells] would have been made by Lilly but for [Wells's] unlawful and unfair competition, and Lilly has suffered financial harm as a direct result of [Wells's] unlawful and unfair competition." FAC ¶¶ 52–53. Lilly also alleged reputational injury: Wells's "unlawful sales of its purported tirzepatide drugs are also injuring Lilly's reputation because of [Wells's] business and trade practices that jeopardize public health." FAC ¶ 54. Accordingly, the Court denies Wells's standing argument.

II. Preemption

Wells's main argument is that Lilly's FDUTPA claim is preempted by federal law. Pursuant to Section 505 of the FDCA, most prescription drugs require premarket approval by the FDA in order to be sold. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). However, the FDCA creates an exception to this premarket approval requirement for qualifying compounding outsourcing facilities. *See* 21 U.S.C. § 353b ("[Section 355(a)] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility."). In addition, 21 U.S.C. § 337(a) bars private enforcement of the FDCA. As such, Wells argues that because the FDCA explicitly authorizes the sale of compounded drugs without premarket approval, Lilly's claim is preempted.

After carefully reviewing the relevant case law, particularly *Novo Nordisk, Inc. v. Brooksville Pharmaceuticals Inc.*, No. 8:23-CV-1503-WFJ-TGW, 2023 WL 7385819, at *1 (M.D. Fla. Nov. 8, 2023)—which relied upon *Nexus Pharmaceuticals Inc. v. Central Admixture Pharmacy Services.*, 48 F.4th 1040, 1044 (9th Cir. 2022)—the Court agrees with Wells that Lilly's FDUTPA claim is preempted on the face of the Amended Complaint. Notably, unlike the cases Lilly relies upon, *Nordisk* and *Nexus* involved similar facts and legal claims.

In *Nordisk,* Novo Nordisk, as the only FDA-approved seller of the drug semaglutide, sued a compounding pharmacy claiming that the sale of unapproved compounded semaglutide violated the FDUTPA and the DCA. The court determined that Novo Nordisk

was essentially calling upon the court to adjudicate whether the defendant compounding pharmacy had complied with the FDCA. Emphasizing the FDCA's prohibition of private enforcement, the court held that the FDUTPA claim was clearly preempted and dismissed the suit. *See* 2023 WL 7385819, at *2-*3.

In *Nexus*, the Ninth Circuit considered a cause of action similar to the instant case. Nexus Pharmaceuticals sued a compounding pharmacy for manufacturing drugs that were allegedly copies of Nexus's FDA-approved drug, Emerphed. *Nexus*, 48 F.4th at 1044. Nexus cited multiple state statutes, including the Florida Drug and Cosmetic Act, that "prohibit the sale of drugs not approved by the FDA." *Id.* The Ninth Circuit held that these types of claims are akin to private enforcement of the FDCA and therefore preempted. *Id.* at 1049.

Another recent case that is highly persuasive is from a district court in the Southern District of Texas that adopted the reasoning of the Ninth Circuit and held that the state law unfair competition claims brought by the plaintiff drug manufacturer, Zyla Life Sciences, against the defendant compounding pharmacy were preempted by the FDCA. Wells discusses this case in its motion and points out that, like Lilly, Zyla was the only FDA-approved seller of a particular drug. The defendant sold a compounded version of Zyla's drug pursuant to Section 503 of the FDCA. Seeking to enjoin the defendant's sales, Zyla filed claims under six states' unfair competition laws, including the FDUTPA. Zyla further argued, like Lilly here, that preemption was inappropriate because the defendant did not comply with section 503A's requirements. The court disagreed and found that Zyla's FDUTPA claim "hinged" on FDCA compliance despite not explicitly alleging that the defendant violated the FDCA, and therefore Zyla's claims impermissibly sought to enforce

requirements that added to the FDCA. For this reason, the FDUTPA claims were preempted and dismissed with prejudice. *See Zyla Life Sciences, Inc. v. Wells Pharma of Houston, LLC*, No. 4:22-cv-4400, 2023 WL 6301651, at *1 (S.D. Tex. Sept. 27, 2023).

The cases Lilly relies on have no bearing on the instant dispute. As Wells points out, in *Mink*, *Godelia*, and *Jacob*, the Eleventh Circuit addressed whether the plaintiffs' state law negligent manufacturing defect claims were preempted by the FDCA's Medical Device Amendments. The Eleventh Circuit determined the claims were not impliedly preempted because "the duty enforced here is the traditional state tort duty of a manufacturer to use due care in manufacturing." Lilly does not allege any claim based on Florida tort law. Instead, Lilly's FDUTPA claim is based on a violation of the FDCA, and is therefore preempted.

III. Failure to State a Claim

Wells's third and final argument is that Lilly fails to allege any facts establishing that Wells Pharmacy's sale of compounded tirzepatide injections is immoral or that consumers have suffered substantial harm from Wells Pharmacy's actions in order to state a plausible FDUTPA claim. While the Court need not address this argument since it concludes the FDUTPA claim is preempted, for the sake of any appeal, the Court agrees with Wells that the alleged facts are insufficient to state a claim. To briefly summarize, there are no facts describing how Wells's sale of compounded tirzepatide is unlawful or unfair other than Lilly's say so.

Finally, while amendment should be freely given at this stage under Fed. R. Civ. P. 15(a), the Court concludes that any further amendment of the complaint would be futile.

Also, it is notable that Lilly did not seek amendment as an alternative to a dismissal with prejudice in its response.

Accordingly, it is ORDERED AND ADJUDGED that:

1. Defendant's Motion to Dismiss (Dkt. 23) is granted.
2. The Amended Complaint is dismissed with prejudice.
3. The Clerk of Court is directed to close this case.
4. Any pending motions are terminated as moot.

DONE and **ORDERED** in Tampa, Florida, this February 5, 2024.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies provided to:
Counsel/Parties of record